November 23, 1999

FDA - Dockets Management Branch (HFA-305)
5630 Fisher's Lane Room 1061
Rockville, Maryland 20852

RE: Docket's # 99D-4488 and 99D-4489

To The Honorable Margaret M. Dotzel and the members of the Department of Health and Human Services

Greetings:

We, the undersigned medical providers of the Vernon County Health Community wish to voice our profound concern regarding the "Guidance for Industry" contained within dockets # 99D-4488 and 99D-4489. It is quite apparent after reviewing the issues at hand, that this policy is not only inadequate but could potentially be quite injurious to consumers of sprouts.

The FDA seems to be promoting a "chemical" solution rather than a "quality" solution to this problem. Primarily, the FDA is now recommending that all sprout seeds be bleached to destroy any bacteria present prior to sprouting. There are several problems with this approach:

1. It does nothing to address the quality of the "raw material" of the entire process, the seeds themselves.
2. Even if the bleaching process were to kill off pathogenic bacteria, it would also kill off any beneficial flora that might be present in the seeds originally and that would otherwise be preserved through the usual sprouting process.
3. There more than likely will be some residual of sodium hypochlorite within the sprouts processed with bleach and we sincerely feel that U.S. consumers are barraged with enough chemicals as it is, and it is foolish to intentionally expose them to more.
4. If this policy were adopted, there would be millions of gallons of additional pollution presented to our environment in the form of bleach and the byproduct, Dioxin (a known carcinogen).

Furthermore, the recommendation that all sprout growers have an in-house laboratory to insure compliance with these new guidance regulations is unreasonable. The vast majority of sprout growers are small operations and they would not be able to absorb the cost. This is, in effect,

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another push for large corporate agribusiness. Obviously, if there was a definite and irrefutable benefit to the American consumer to follow this path, we would have to agree with it, but we firmly believe that the recommendations, as they stand, will instead create a significantly greater risk of harm to the consumer while simultaneously harming small American businesses.

We do not presume to tell the FDA its business. However, we are intimately concerned with the health of our patients and we believe that our opinions are medically sound. We recommend that you scrutinize your data once again. We ask you, has there ever been an organic sprout company utilizing "raw materials" of the highest quality, which has ever had an incident of bacterial contamination in their sprout products? Doesn't it only make sense to start with the highest quality raw material and insure that the potential source of contamination is minimized at the very beginning of the process? Doesn't it only make sense to minimize consumer exposure to potentially toxic and carcinogenic chemicals? Doesn't it only make sense to avoid burdening our envioronment with millions more gallons of polutants?

At the very least, the FDA should add to the guidance clause which states that certified organic, or seeds certified by the FDA as fit for human consumption, are considered an acceptable alternatives to prevention of microbial hazards in sprouted seeds.

We are optimistic that if you consider these concerns of ours you will come to similar conclusions. Our patients and your citizens/consumers deserve the best approach to this problem. Please let common sense and good scientific judgement prevail.

Cordially and respectfully,

MSH/am

(Over)

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